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(54) **Test sample envelope**

(57) Test devices comprise a first sheet having at least one aperture therein; a second sheet; an intermediate sheet carrying a test reagent located between the first and second sheets and having a portion exposed by the said aperture(s); and a cover sheet suitable for covering the said aperture(s); the side of the cover sheet adjacent to the first sheet and/or the side of the first sheet adjacent to the cover sheet having adhesive means which enable the first sheet and cover sheet to be adhesively bonded together to seal off the aperture(s) and any test material applied thereto from the atmosphere. The device may include on the underside of the second sheet a flap which when raised allows introduction of reagent to the test material. The adhesive means preferably comprises an adhesive composition which is capable of being activated when desired, e.g. by the removal of a protective layer. The above test devices are particularly useful for the detection of a substance or substances in stool samples.

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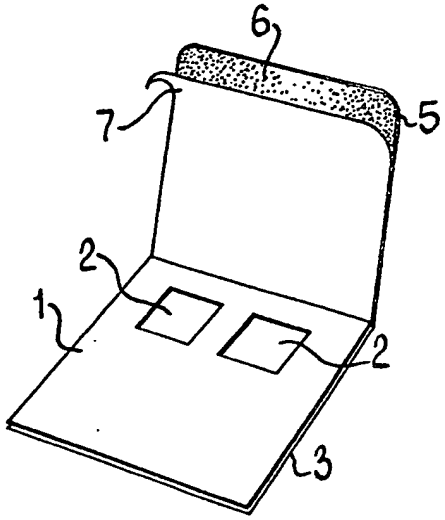

Fig.1

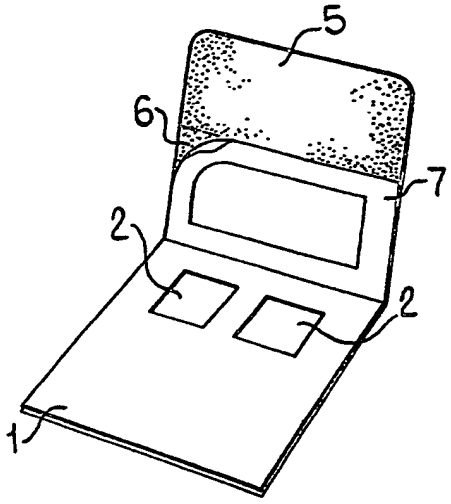

Fig.2

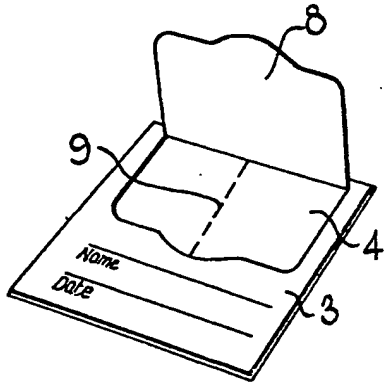

Fig.3

SPECIFICATION

Test devices

The present invention relates to test devices.

For some years medical diagnostic practice has made use of so-called test strips which enable diagnostic evidence, for example on the presence or absence of certain substances characteristic of particular anomalies or disease patterns to be furnished quickly and at low cost.

The use of test strips for detecting occult blood in stools may be mentioned as one example of such test strip methods. Test strips (also known as test envelopes) designed for the detection of occult blood in stools have been proposed for example in U.S. Patent Specification 3,996,066 and in German utility model GM 7720665.

The test envelope described in the above-mentioned Specification consists essentially of a front sheet with several apertures or holed; a rear sheet; and intermediate reagent sheet located under each of the openings and carrying a test reagent; a cover flap suitable for covering, at least in part, the front sheet including the openings, the rear sheet being constructed partly as a flap which, when opened, exposes the underside of the reagent sheet at least in the region below the apertures; and a fastening device, for example a lug situated on the cover flap and a corresponding slit passing through the front and the rear cover sheets.

The reagent sheet carrying the test reagent consists, as a rule, of a suitable filter paper which has been impregnated with the test reagent, generally guaiacum resin in the case of detection of occult blood in stools. The remaining parts of the test envelope generally consist of cardboard, althougn the use of this material is not essential. The test is conducted, as a rule, by applying and thinly distributing stool samples on the face of the aperture, for example using a spatula or die. With test envelopes having several apertures, samples from different regions of the stool may be applied. This part of the test may be carried out by the patient himself. After closure (by pushing the lug of the cover flap into the slit) the test envelope is given to the physician. The flaps on the rear sheet are then opened and the physician applies the developer on to the thus exposed parts of the reagent sheet (appropriately underneath the apertures now carrying the stool samples on the other side). If a guaiacum resin is used in the reagent layer, a peroxide solution is employed as developer. A blue to blue-green colouring indicates the presence of blood, more precisely haemoglobin.

The test envelopes used in practice generally meet the requirements for diagnostic detection and ease of handling. However, there are certain possibilities for improvement, e.g. as illustrated by the test envelopes described in U.S. Patent Specification No. 3,996,066 or German utility model GM 7720665.

As already mentioned, after the stool has been applied on to the openings, the test envleope is closed mechanically, namely by pushing the lug of the cover flap into the slit. The test envelope may then be prepared for dispatch, for example by placing it in a plastic bag of suitable dimensions which is then sealed. After reaching the physician the test envelope is then removed from the bag and developed.

After it has been applied to the reagent layer, the stool sample often tends to dry out to a considerable extent. On the one hand, this drying-out effect is desirable, since haemoglobin decomposition in the stool sample is thereby delayed or even prevented. On the other hand, the "mechanical" closure of test envelopes of conventional construction does not guarantee that the dried stool cannot escape from the test envelope at least in traces, for example as dust. This possibility is unsatisfactory particularly since it may occur in such locations as public health centres, physician's premises and clinics.

We now have found that test envelopes of the above-described type, e.g. for the detection of occult blood in stools, can be produced in which the escape of stool samples, even in traces, can be reduced or prevented.

According to the present invention we provide test devices comprising a first sheet having at least one aperture therein, a second sheet; an intermediate sheet carrying a test reagent located between the first and second sheets and having a portion exposed by the said aperture(s); and a cover sheet suitable for covering the said aperture(s); the side of the cover sheet adjacent to the first sheet and/or the side of the first sheet adjacent to the cover sheet having adhesive means which, when desired, may be activated thereby enabling the first sheet and cover sheet to be adhesively bonded together to seal off the aperture(s) and any test material applied thereto from the atmosphere.

The above test devices are advantageously used for detecting substances in stool samples and the reagent is therefore selected accordingly.

The adhesive means in the above-described test devices may for example comprise an adhesive composition applied to at least the peripheral portion of the said side of the cover sheet and/or at least the peripheral portion of the said side of the first sheet, the said composition being capable of being activated when desired. The adhesive composition may for example be covered with a protective layer which may be removed when it is desired to effective adhesive bonding between the cover sheet and the first sheet.

Advantageously, the adhesive composition is applied to those portions of the said sides of the cover sheet which, after adhesive bonding, are adhesively bonded to the portions of the front sheet located between the said aperture and the periphery of the said sheet, generally in the lower half of the cover sheet, such potions being advantageously 10 to 15 mm in width.

It is necessary to ensure that any adhesive which may come in contact with the applied stool is completely inert, for example in the test for detection of occult blood or other determinations. The adhesive composition may contain, if desired, bactericidal or bacteriostatic agents which do not interfere with the test reaction and which are otherwise

harmless, thus providing an aditional hygienic safeguard which also favours the reliability of the test.

We have found that conventional adhesive compositions are generally inert so far as the above test requirements are concerned. Thus, adhesive compositions known from other fields of application, for example adhesive labels, plasters, etc. and provided with a removable cover layer of an impregnated paper or plastic film may be employed in the test devices according to the present invention.

Although the use of the above-described protection layer(s) is preferred for the activation of the adhesive means, activation can be effected by other methods, e.g. by moistening.

The test devices according to the present invention will now be described with reference to the accompanying drawings in which Figures 1 and 2 are perspective views of two preferred embodiments and Figure 3 is a perspective view of the back of Figures 1 and 2.

Referring to Figures 1 and 2 the test envelope consist of a first sheet (1) with two apertures (2) which may be round or of another regular geometry, but are preferably square as shown; a second sheet (3), an intermediate reagent sheet (4) lying between them and impregnated with the test reagent for detecting substances in stools, and cover flap (5). The inside of the cover flap (5) is covered, for example over its entire face with an adhesive layer (6) provided with a protective layer (7) which may be removed for the purpose of adhesively bonding the first sheet (1) to the cover flap (5). In the illustration according to Figure 1 the protective layer (7) has just been detached to expose the adhesive layer (6).

In Figure 2, the adhesive layer (6) with the removable protective layer (7) covering it may be designed so that the adhesive layer (6) forms a kind of frame in the region of the lower half of the inside of the cover flap (5) in such a way that in the bonded state the gaps between the apertures (2) and the margins of the first sheet (1) are sufficiently sealed. A sufficient bonding is provided, for example if the width of the "frame" is about 10 to 15 mm.

It is of particular advantage in the form of construction according to Figure 2 that one may employ conventional adhesive closures where the adhesive is activated as required, for example by the removal of a protective layer.

As shown in Figure 3, a flap (8) which, in the open position, exposes the underside of the reagent sheet (4), is situated on the second sheet (3) in the region of the apertures. Development is effected in conventional manner from this underside by the application of the developer.

CLAIMS

1. Test devices comprising a first sheet having at least one aperture therein; a second sheet; an intermediate sheet carrying a test reagent located between the first and second sheets and having a portion exposed by the said aperture(s); and a cover sheet suitable for covering the said aperture(s); the side of the cover sheet adjacent to the first sheet and/or the side of the first sheet adjacent to the cover sheet having adhesive means which, when desired, may be activated thereby enabling the first sheet and cover sheet to be adhesively bonded together to seal off the aperture(s) and any test material applied thereto from the atmosphere.

2. Test devices as claimed in claim 1 wherein tbe said adhesive means comprise an adhesive composition applied to at least a peripheral portion of the said side of the cover sheet and/or the at least a peripheral portion of the said side of the first sheet, the adhesive composition being activatable when desired.

3. Test devices as claimed in claim 2 wherein the adhesive composition is applied to at least a peripheral portion of the said side of the cover sheet, the adhesive composition being covered with a protective layer which may be removed when it is desired to effect adhesive bonding between the said cover sheet and the first sheet.

4. Test devices as claimed in claim 3 in which the said protective layer comprises an impregnated paper or plastic film.

5. Test devices as claimed in any of claims 2-4 wherein the adhesive composition is applied to those portions of the said side of the cover sheet which, after adhesive bonding, are adhesively bonded to the portions of the first sheet located between the said aperture and the periphery of the said first sheet.

6. Test devices as claimed in claim 5 wherein the distance between the said aperture and the periphery of the first sheet is 10 to 15 mm.

7. Test devices as claimed in any of claims 2 to 6 wherein the said adhesive composition contains at least one bactericidal or bacteriostatic agent.

8. Test devices as claimed in any of the preceding claims for detection of a substance or substances in stool samples wherein the said test reagent is one selected for this purpose.

9. Test devices as claimed in claim 1 substantially as herein described.

10. Test devices substantially as herein described with reference to the accompanying drawings.

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